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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/436,076	11/08/1999	DENISA D. WAGNER	10861/011003	6116

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	24

DATE MAILED: 06/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/436076	WAGNER ET AL
	Examiner	Art Unit
	GAMBEL	1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 2/26/01

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 40, 41, 45, 49-52, 56, 59-60, 73, 74

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 40, 41, 45, 49-52, 56, 59, 60, 73, 74

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☑ Notice of References Cited (PTO-892)	4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)	5)☐ Notice of Informal Patent Application (PTO-152)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6)☐ Other:

DETAILED ACTION

1. Applicant's election with traverse of Group IV (PSGL-1) in Paper No. 22 is acknowledged. The traversal is on the ground(s) that PSGL-1 mimics and P-selectin mimics are classified in the same Class 514, subclass 2 and can be searched coextensively. This is not found persuasive because of the reasons of record. As pointed out in the previous Office Action (Paper No. 20). The restriction claims are drawn to patentably distinct methods relying upon patentably distinct products. The methods rely upon P-selectin ligands such as sialyl Lewis x, sialyl Lewis a, P-selectin, PSGL-1, 160 kD monospecific P-selectin ligand, P-selectin mimic or P-selectin mimic or antibodies thereto which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. In contrast to applicant's reliance on Class, subclass alone, the claimed methods employ various PSGLs which are distinct because their structures and modes of action are different, which require non-coextensive searches. These PSGLs are different with respect to biochemical properties; including primary, secondary and tertiary structure. These molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-39, 42-44, 46-48, 53-55, 57-58 and 61-72 have been canceled previously.

Claims 40-41, 45, 49-52, 56, 59-60 and 73-74 are pending.

Claims 40-41, 45, 49-52, 56, 59-60, 73-74 are being acted upon as the elected invention.

Claims 40-41, 49-52, 59-60, and 73-74, as they read on Groups I-III and V-XIII are withdrawn from consideration by the examiner 37 CFR 1.142(b), as being drawn to a nonelected inventions.

Applicant should provide a clean set of claims that read on the elected invention which reads on Group IV (PSGL-1).

2. Any objection or rejection of record which is not expressly repeated in this action has been overcome by applicant's response and withdrawn.þ

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Applicant should restrict the title to the claimed invention.

4. The Abstract of the Disclosure is objected to because it does not adequately describe the claimed invention. Correction is required. See MPEP 608.01(b).

5. The application is required to be reviewed and all spelling, TRADEMARKS, and like errors corrected.

6. Claims 40-41, 45, 49-52 and 73-74 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 40-41, 45 and 49-50 are indefinite in the recitation of "at least partially preventing or reversing" because this "phrase" is relative in nature which renders the claims indefinite. The "phrase" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

B) Claims 40-41, 49-52, 59-60, 73-74 are indefinite in the recitation of "P selectin ligand" in that they only describe the product(s) in the claimed methods of interest by an arbitrary molecule name. While the name itself may have some notion of the activity of the protein, there is nothing in the claims which distinctly claims the protein and fragments thereof. Applicant should particularly point out and distinctly claim the "PSGL" and variants thereof" by claiming sufficient characteristics associated with the protein (e.g. activity, molecular weight, amino acid composition, N-terminal sequence, etc.). Claiming biochemical molecules by a particular name given to the protein by various workers in the field fails to distinctly claim what that protein is and what the compositions are made up of.

Applicant should amend the claims to recite PSGL-1 or P-selectin glycoprotein ligand-1 to read on the elected invention as well as to clearly define the claimed invention as it reads on a recognized P selectin ligand.

C) The applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 40-41, 45, 49-52, 56, 59-60, 73-74 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cummings et al. (U.S. Patent No. 6,309,639) in view of Tedder et al. (U.S. Patent No. 5,834,425) and Coller et al. (U.S. Patent No. 5,976,532).

Cummings et al. teach the clinical applications, including atherosclerosis and ischemia, myocardial infarction and reperfusion injury, by inhibiting platelet-leukocyte interactions with PSGL-1 and fragments thereof (see entire document, including Clinical Applications on columns 18-22 and Claims). Cummings et al. teach that the therapeutic use that reduce leukocyte adherence in ischemic myocardium can significantly enhance the therapy efficacy of thrombolytic agents (see column 18, paragraph 7).

Cummings et al. differs from the claimed invention by not disclosing the art know use of chimeric forms of inhibitory selectin based therapeutics and by not disclosing the various art known vessel-corrective techniques encompassed by the claimed invention.

Tedder et al. teach the art known generation and use of chimeric peptides combining ligand binding portions of selecting based inhibitory therapeutics, including those based upon P-selectin, with other molecules such as immunoglobulin to increase serum half-life or avidity of the therapeutic agent to block platelet or leukocyte-mediated inflammation (see entire document, including Use on columns 10-14). Similar to Cummings et al. And art known practice at the time the invention was made, Tedder et al. Teach combination therapy (see column 13, paragraph 1).

Given the art known practice and desire to increase the avidity and/or half-life of therapeutics in general, including selectin-mediated inhibitors, as taught by Tedder et al., one of ordinary skill in the art would have been motivated to modify the PSGL-1 and fragments thereof taught by Cummings et al. By making chimeric constructs thereof in the treatment of cardiovascular disorders.

Coller et al. teach the art known vessel-corrective techniques at the time the invention was made in the treatment of cardiovascular disorders such as atherosclerosis and restenosis, including angioplasty, atherectomy and coronary bypass surgery (see Background of the Invention on column 1 and Utility of Platelet-specific Chimeric Immunoglobulin on columns 5-7). In teaching the use of an inhibitor of platelet aggregation and thrombus formation associated with such conditions, Coller et al. teach the art known use of combination therapy with other drugs such as thrombolytic agents and that the amounts administered before, along with or subsequent to treatment will depend on a variety of factors and clinical symptoms known to the ordinary artisan at the time the invention was made (see column 6, paragraphs 2-3).

Given the art known practice of combination therapy, as taught by Cummings et al., Tedder et al. and Coller et al. as well as the art known practice of vessel-occlusive techniques to treat atherosclerosis and restenosis, as taught by Coller et al., one of ordinary skill in the art would have been motivated to administer the PSGL-1 and fragments thereof, as taught by Cummings et al. in various vessel-occlusive techniques given its properties of inhibiting platelet-leukocyte interactions for various clinical applications, including atherosclerosis and ischemia, myocardial infarction and reperfusion injury, as taught by Cummings et al. with an expectation of success. Given the art known practice of modes of administrations and dosing depending on a variety of factors and clinical symptoms known to the ordinary artisan at the time the invention was made, as taught by Coller et al. In cardiovascular diseases, the claimed limitations were met or would have been obvious variants in meeting the needs of the patients in order to achieve a therapeutic effect depending on the symptom at the time the invention was made.

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
June 6, 2002